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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,757	10/18/2001	Carol T. Schembri	10004108-1	7503

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AGILENT TECHNOLOGIES, INC.
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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,757

Applicant(s)

SCHEMBRI ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,12-20,22-24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,12-20,22-24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 21 September 2004 in which the specification and claims 1, 3-4, 14-16 and 19 were amended, claims 11, 21 and 25 were canceled and claim 26 was added. All of the amendments have been thoroughly reviewed and entered.

The previous objections and rejections in the Office Action dated 11 May 2004, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 1-10 12-20 22-24 and 26 are under prosecution.

Claim Rejections - 35 USC § 112

First paragraph of 35 U.S.C. 112: Enablement

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claims are drawn to a plastic base layer having a fluorescence of at least 10 reference units. While the specification is enabling for the an array assembly having a plastic base layer, claimed reference units are not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirements and whether undue experimentation would be required to make and use the claimed invention (see *In re Wands*, 858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404, 1988). These factors include but are not limited to:

Nature of the Invention

The claims are drawn to an array assembly comprising a plastic base layer having a fluorescence of at least 10 reference units. The nature of the invention is such that units of fluorescent measurement requires some unit standard or standard of measurement.

The specification at page 9, lines 11-20 describes "reference unit":

"Reference unit" in relation to fluorescence measurements herein means the maximum fluorescence obtainable from a fused silica, or one-third the maximum value obtainable from a borosilicate glass. All fluorescence measurements herein, unless otherwise indicated, are integrated fluorescence emission energies from 547 nm to 597 nm, which result from a 1 mm thick section of material, using a monochromated high pressure Xe lamp excitation source centered at 532 nm with a width at half-maximum of about 5 nm. All ratios assume the same unit area of illuminated material. The following may be used as the foregoing referenced materials (available from the National Institute of Standards and Technology, Maryland, U.S.A.): fused silica - Standard Sample 198; borosilicate glass-Standard Reference Material 93a.

The above description does not describe numerous elements required to define "reference unit" in such a way as to enable one of skill in the art to make and use the claimed invention. The missing elements include the type of Xe lamp used in the measurement. The

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type of lamp would be essential because the lamps differ by voltage and/or power and differences in voltage and/or power result in different emission energies and hence different fluorescent measurements. A second missing element is the geometry of illumination. The geometry includes, angle of illumination, the light path relative to the surface, and the position of the fluorescent detector relative to the surface. All of these influence the amount of fluorescence measured from the glass. Furthermore, it is unclear whether the reference unit is a single value or a variable based on environmental conditions. The nature of the invention is such that units of measurement requires some unit standard or standard of measurement. However, the specification has not described the units so as to enable one of skill in the art to make and use the claimed invention.

State of the Prior Art

The claims are drawn to an array assembly comprising a plastic base layer having a fluorescence of at least 10 reference units. The state of the prior art is such that the claimed reference units are not taught or described in the prior art. Therefore, the reference units are not a known standard of measurement. Because the prior art and instant specification do not or describe the claimed reference units, the claimed invention is not enabled.

Level of Predictability in the Art

The claims are drawn to an array assembly comprising a plastic base layer having a fluorescence of at least 10 reference units. The specification describes "reference unit" at page 9, lines 11-20 as reiterated above. Numerous elements influence fluorescence measurements as discussed above. However, the specification does not teach or describe these elements. Absent a description of elements including type of Xe lamp, geometry of illumination and environmental conditions of illumination, the level of predictability in the art for determining a reference unit as a standard of measurement would be very low.

Existence of Working Examples

The specification does not teach working examples of the claimed reference units.

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Quantity of Experimentation Required

The claims are drawn to an array assembly comprising a plastic base layer having a fluorescence of at least 10 reference units. In view of the nature of the invention in which units of fluorescent measurement requires some unit standard or standard of measurement; in view of the state of the prior art which does not teach or describe the claimed reference unit; in view of the of unpredictability in the art with regard to providing a reference unit of fluorescence measurement; and in view of the lack of working examples of the claimed invention, it would require undue experimentation for one skilled in the art to make and use the invention as claimed.

Response to Arguments

4. Applicant cites the specification's definition of "reference unit" as an enabling teaching to the claimed "at least ten reference units". Applicant asserts "the definition is tied to the maximum fluorescence obtainable, or a fraction thereof, this necessarily means that one used the Xe lamp in a manner that provides the maximum fluorescence when determining units. As such, one of skill in the art would find these claims fully enabled". The argument has been considered but is not found persuasive. The cited passage is noted and was discussed in the previous office action. However, the passage does not define, describe or enable the claimed "at least ten reference units" or any numerical value of reference units. The claimed "at least ten reference units" requires a teaching of reference unit measurement such that one of skill would be enabled to determine/measure reference units quantitatively i.e. determine five reference units or seven reference units etc. However, the specification has not provided any quantitative teaching whereby such unit measurement could be performed. Lacking such a teaching, the specification does not enable one of skill in the art to make and use the invention as claimed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-5, 7, 9, 13-16, 18, 24 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Dickinson, T. (WO 01/18524, published 15 March 2001).

Regarding Claim 1, Dickinson discloses an array assembly comprising a plastic base layer e.g. plastics or optical fiber bundles (page 10, line 32), a glass layer forward of the base plate i.e. glass microspheres (page 16, lines 7 and 10), an array of polymers having a pattern of features on a front surface of the glass i.e. biopolymers immobilized on the arrayed microspheres (page 8, lines 15-22) and a layer between the base and glass layers that blocks illuminating light from reaching the plastic base (page 11, lines 18-25) and wherein the array assembly is flexible i.e. fiber optic bundles (page 10, line 32).

Regarding Claim 2, Dickinson discloses the array wherein the polymers are biopolymers (page 16, lines 24-34).

Regarding Claim 3, Dickinson discloses the array wherein the layer between the glass and plastic is opaque (page 11, lines 20-21).

Regarding Claim 4, Dickinson discloses the array wherein the layer between the glass and plastic is reflective (page 11, lines 20-21 and 24-25).

Regarding Claim 5, Dickinson discloses the array wherein the reflective layer comprises a metal (page 11, lines 20-21).

Regarding Claim 7, Dickinson discloses the array wherein the glass layer has a thickness of 40-200nm (page 16, lines 17-20).

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Regarding Claim 9, Dickinson discloses the claimed assembly is defined as having a base layer that absorbs at least 10% of light at 532 nm. The recitation describes functional aspects of the layer but does not describe structural components. Because the claim does not further limit the structures of Claim 4 and because Chen discloses the structural limitations recited in Claim 4, Chen also discloses the assembly as claimed.

Regarding Claim 13, Dickinson discloses the assembly comprising multiple arrays along the front surface e.g. sub-arrays (page 35, lines 16-24).

Regarding Claim 14, Dickinson discloses a method of fabricating an array assembly comprising providing a plastic base i.e. fiber optic bundle (page 10, line 32) with a glass layer forward of the base plate i.e. glass microspheres (page 16, lines 7 and 10) and forming an array of polymers having a pattern of features on a front (upper) surface of the glass (e.g. page 8, lines 15-34).

Regarding Claim 15, Dickinson discloses the array wherein the layer between the glass and plastic is reflective (page 11, lines 20-21 and 24-25).

Regarding Claim 16, Dickinson discloses the array wherein the reflective layer comprises a metal (page 11, lines 20-21).

Regarding Claim 18, Dickinson discloses the array wherein the glass layer has a thickness of 40-200nm (page 16, lines 17-20).

Regarding Claim 24, Dickinson discloses the array wherein the polymers are peptides or polynucleotides (page 16, lines 24-34).

Regarding Claim 26, Dickinson discloses the array wherein the layer between the glass and plastic is opaque (page 11, lines 20-21).

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7. Claims 6 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Dickinson, T. (WO 01/18524, published 15 March 2001) as defined by Academic Press Dictionary of Science and Technology, Morris, C.G. ed. Academic Press, Inc. San Diego, 1992, page 634).

Regarding Claim 6 and 17, Dickinson discloses the assembly comprising multiple layers e.g. plastics or optical fiber bundles (page 10, line 32), glass microspheres (page 16, lines 7 and 10) and dielectric coating (page 12, lines 8-9). Academic Press Dictionary of Science and Technology cites glass and plastic as examples of dielectric materials. Hence, Dickinson discloses the assembly comprising multiple layers of dielectric material as claimed.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 10, 12, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson, T. (WO 01/18524, published 15 March 2001) in view of Chen et al (U.S. Patent Application Publication No. 2001/0051714, filed 10 January 2001).

Regarding Claims 10 and 20, Dickinson discloses an array assembly comprising a plastic base layer e.g. plastics or optical fiber bundles (page 10, line 32), a glass layer forward of the base plate i.e. glass microspheres (page 16, lines 7 and 10), an array of polymers having a pattern of features on a front surface of the glass i.e. biopolymers immobilized on the arrayed microspheres (page 8, lines 15-22) and a layer between the base and glass layers that blocks

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illuminating light from reaching the plastic base (page 11, lines 18-25) and wherein the array assembly is flexible i.e. fiber optic bundles (page 10, line 32). Dickinson further teaches the array and method comprising an identifier i.e. fiducial (page 27, lines 25-34) but is silent regarding a back-surface position of the identifier.

However, Chen et al teach a similar array and method comprising a plastic base layer a glass layer forward of the base plate i.e. flexible fiber optic (§ 66-7), and an array of polymers having a pattern of features on a front (upper) surface of the glass (§ 57) wherein the assembly further comprising an identifier at position selected based on the shape of the base e.g. on the back of the base layer (§ 118). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to position the identifier of Dickinson to the back of the base layer based on the shape of the base as taught by Chen et al (§ 118).

Regarding Claim 12 and 22, Dickinson teaches the base is an optical fiber (page 10, line 32) but is silent regarding the form or shape of the base. Chen et al teach the similar array comprising an optical fiber base wherein the optical fiber base is in the form of an elongated web i.e. elongated (e.g. § 10-11). Hence, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made that the optical fiber of Dickinson would have been elongated. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the base of Dickinson to provide the elongated substrate as taught by Chen et al for the expected benefit of improved hybridization efficiency (§ 28-30) based enhanced chance for probe-target interaction as the elongated substrate moves through sample fluid.

Regarding Claim 23, Dickinson does not teach depositing drops onto the surface of the glass layer. However, Chen teaches the similar method wherein deposition of drops onto the substrate provides continuous, high-speed, mass production of arrays (§ 114). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the drop deposition of Chen et al to the array construction of Dickinson for the expected

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benefit of providing continuous, high-speed, mass production of arrays as taught by Chen et al (¶ 114).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/285,759. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an array assembly and methods of making same. The claims differ only in the arrangement of the limitations within the claim sets. For example, instant claim 1 is drawn to an array assembly comprising a base layer and glass layer and dependent claim 4-5 limit the assembly to further comprising a reflective/metal layer and dependent claim 11 limits the assembly to flexible. Claim 1 of the '759 application includes the reflective and flexible limitations. The claims further differ in that Claims 3, 10, 11, 17 are drawn to species of plastic and glass while independent Claim 1 of the instant application is drawn to the genus of plastic and glass.

The courts have stated that a genus is obvious in view of the teaching of a species see *Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

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Because the courts have stated that a genus is obvious in view of a species and because the claim sets differ only in the arrangement of the limitations, the instantly claimed invention would have been obvious view of the invention of claims in the '759 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response

Applicant's Terminal Disclaimer is acknowledged. However, the Terminal Disclaimer is disapproved by the office. At the time of this action, the examiner was unable to determine the grounds for disapproval. The rejection is maintained until a Terminal Disclaimer is approved.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 29, 2004